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September 12, 2002

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BERNARD SANDERS, VERMONT,
INDEPENDENT

The Honorable Tommy G. Thompson
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

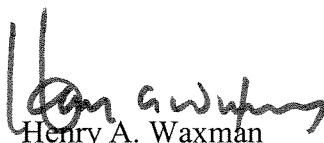
Thank you for discussing colored contact lenses with me on Tuesday. I am pleased to hear you will personally oversee the decision on whether to reclassify these products as cosmetics. I am hopeful that you will agree that such a change in longstanding policy would risk an epidemic of serious eye injuries in American children and is simply not necessary as a matter of law.

I also would like to bring to your attention the consensus of patient, health professional, and industry groups in support of the agency's longstanding position that colored lenses are prescription medical devices. The health groups include the American Academy of Ophthalmology, the American Optometric Association, the Contact Lens Association of Ophthalmologists, and the American Academy of Pediatrics. The industry groups include the Contact Lens Institute, which represents all of the major manufacturers of colored lenses, and CIBA Vision, which is the largest manufacturer of the colored lenses now on the market. Also opposed to any change in policy is Prevent Blindness, the nation's largest advocacy organization devoted to eye health and safety.

Statements from each of these groups on colored contact lenses are attached to this letter. I am also making these materials available to the public on my web site.

Please do not hesitate to contact me if I can provide any additional information or to discuss this question further.

Sincerely,



Henry A. Waxman
Ranking Minority Member

Enclosures



August 22, 2002

Lester M. Crawford, DVM, PhD.
Deputy FDA Commissioner
Food and Drug Administration
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Rockville, MD 20857

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Washington, DC 20005-3570

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FEDERAL AFFAIRS DEPARTMENT

Dear Dr. Crawford,

It has come to our attention that the FDA is looking at the issue of regulation of Nonprescription Contact Lenses. There is growing concern among the membership of the American Academy of Ophthalmology about the risks to the public from use of these nonprescription lenses resulting in the attached warning released in July (attached). We strongly support FDA policy that regulates these lenses as medical devices and want to work with you to ensure that the policy is in the best interest of the public health.

Historically, all contact lenses, including tinted and costume lenses, have been considered and evaluated as medical devices by the U.S. Food and Drug Administration. Further, FDA requires a prescription from an eye health care professional, such as an ophthalmologist. Just because the cosmetic lenses have no power in them does not preclude the necessity of insuring a good fit of the lens to the cornea, which can only be performed by an eye care professional. Although contact lenses provide visual and cosmetic benefits, their use carries some risk of ocular complications, the most serious being microbial keratitis, which can lead to vision loss. Thus, proper evaluation and fitting and instruction on the care, cleaning and wear of contact lenses is important to reduce the risk of ocular complications.

Risks associated with improper wear, care and cleaning of contact lenses include allergic reactions, bacterial infections, corneal abrasions and corneal ulcers, and other changes such as epithelial keratopathy, corneal thinning, corneal neovascularization, and corneal warpage. In some patients, contact lenses may not be advisable because of significant pre-existing conditions such as eyelid abnormalities, tear film, or cornea abnormalities.

In view of problems we are seeing related to these nonprescription lenses, I would hope that the FDA would give this issue long and careful review. Thank you for your consideration. Please do not hesitate to contact Catherine Cohen in our Washington office or myself, if we can be of assistance.

Sincerely,

William Rich, III, M.D.
Secretary, Federal Affairs

For Immediate Release**July 10, 2002****American Academy of Ophthalmology Warns Young People at Risk of Eye Damage from Use of Nonprescription Contact Lenses**

(San Francisco)—Recently, ophthalmologist Gail Royal, MD, of Myrtle Beach, S.C., saw several teenage and young adult patients in one week. They were all suffering from problems associated with wearing costume and tinted contact lenses they had purchased without prescriptions, mostly from beachwear stores.

"This has become a serious problem in this area," said Dr. Royal. "These contact lenses are very popular among young people. Unfortunately, they don't realize how dangerous contact lenses can be, especially when not handled correctly."

According to the Food and Drug Administration, contact lenses, including costume and tinted lenses, are considered medical devices and must be prescribed by an eye health care professional, such as an ophthalmologist.

"Many people mistakenly think that just because they aren't wearing contact lenses to correct a refractive error, like nearsightedness, they don't need a prescription," said Dr. Terrence P. O'Brien, Associate Professor of Ophthalmology and Director of Ocular Infectious Diseases at the Wilmer Eye Institute, Johns Hopkins Hospital in Baltimore, and a spokesperson for the American Academy of Ophthalmology, the Eye M.D. Association, "but that is not the case. Contact lenses are medical devices that require specific shape parameters for proper fit."

"Also," Dr. O'Brien continued, "it's a pretty safe bet to assume that people buying contact lenses from these beachwear stores aren't being told how to clean and care for the lenses, or how long they can safely be worn," he said. "This can lead to potentially serious complications, including bacterial infections, corneal abrasions, corneal ulcers and allergic reactions. To avoid such problems, it's important that people have their contact lenses fitted properly by an eye health care professional, such as an ophthalmologist. Ill-fitting lenses can result in permanent damage to the cornea, and even vision loss."

Dr. Royal said many of her patients wore the contact lenses all night while at parties or dancing. "Unless contact lenses are made from a special material that allows high oxygen absorption by the cornea, they should never be worn overnight." Furthermore, Dr. Royal emphasized, "We don't even know what materials these contacts are made of, or if they are approved by the FDA. The vials they come in that I've seen have had no labels identifying the manufacturer."

Other problems she encountered resulted from patients' swimming in their contact

lenses, or getting sand in them. She said contact lens wearers also exchange them with each other. "This is really dangerous," she said. "It can lead to the spread of bacteria, viruses, fungi and amoebae that cause eye disease. It is sad that such a frivolous choice can lead to such dire health consequences."

The American Academy of Ophthalmology is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 27,000 members worldwide. To find out more about eye health care, visit the Academy's partner Web site at www.medem.com. To find an Eye M.D. in your area, visit the Academy's Web site at www.aao.org.

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Reporter Contact: Media Relations at 415-561-8534 or by e-mail, media@aao.org

August 27, 2002

BY FAX

*The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201*

Dear Mr. Secretary:

The American Optometric Association has learned with dismay that the Food and Drug Administration (FDA) may be considering reclassifying tinted plano contact lenses as cosmetics instead of medical devices. We are deeply concerned that such a move will unnecessarily endanger the health of the public.

FDA has historically and correctly classified these lenses as prescription devices since it is necessary for an eye care practitioner to evaluate the ocular health of the patient and the fit of the lens to the eye, just as they would for lenses with corrective power. The physical and other characteristics of these lenses are identical to corrective power lenses; the only difference is the refractive power. More importantly, the very real health considerations associated with improper fit and wearing of lenses applies equally to both non-corrective and corrective power lenses.

Earlier this year the potential risk to wearers of these lenses was dramatized when the sale of over-the-counter tinted lenses in Myrtle Beach, South Carolina, led to a rash of eye injuries, some of them quite serious. Reclassifying these lenses to cosmetics will only lead to increased incidents of this nature.

We are puzzled by this proposed change in policy, given the agency's longstanding and proper concern that consumers be aware of and take steps to minimize the risks associated with improper lens wear. For example, the FDA notes on its web site that "Contact lenses that are not properly fitted by an eye doctor might not work well, or even worse, may harm your eyes (Buying Contact lenses on the Internet, by Phone or by Mail, Questions and Answers, May 2001).

As noted earlier, that advice should apply equally to non-corrective and corrective power lenses, since both have the same characteristics and pose the same risks if fitted and worn improperly.

On behalf of the nation's 30,000 plus doctors of optometry and their patients, we urge your immediate intervention to prevent implementation of this ill-founded proposal. The eye health of the public is clearly best served by maintaining FDA's historic policy, based on sound legal reasoning and clinical evidence, of regulating these lenses as prescription medical devices.

Thank you for your consideration.

Sincerely,

*J. Pat Cummings, O.D.
President
American Optometric Association*



Contact Lens Association of Ophthalmologists
An International Educational Association for Refractive Eyecare

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Statement on Contact Lenses as a Medical Device

Bruce H. Koffler, MD, President

August 23, 2002

"Contact lenses are regulated by the US Food and Drug Administration (FDA) due to the fact that these medical devices, although among the safest medical devices ever invented, still can pose a substantial health risk if not properly fitted, cared for and followed up with professional vision care.

It is important to remember that a contact lens is placed on the eye in direct contact with sensitive ocular tissue and surrounded by the eye tear film. This results in the possibility of a lack of oxygen reaching the highly metabolic cornea, a mechanical impact on the cornea, corneal limbus and/or ocular sclera, and perhaps, of most concern of all, the possibility of a bacterial, viral or fungal infection occurring in the eye.

Although many bacteria may be responsible for infection, the one of most concern is *Pseudomonas*, which if not caught early and treated professionally can result in the loss of an eye. Poor hygiene, dirty hands, improper lens care, overnight wear and sharing of lenses, all lead to an increased risk of infection.

Another infection of great concern is that caused by an amoeba of the genus *Acanthamoeba*, a single celled organism found in tap water, hot tubs and soil. An infection by this organism is difficult to treat, and in some instances results in a corneal transplant.

It absolutely does not matter whether a contact lens is prescribed as plano, (a lens with no refractive power which is fit strictly for cosmetic purposes such as to change eye color or to cover an ocular scar), or prescribed with a specified power for vision correction. The physical and physiological impacts are the same, as is the great concern of the possibility of ocular infection."

September 9, 2002

Honorable Tommy G. Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson:

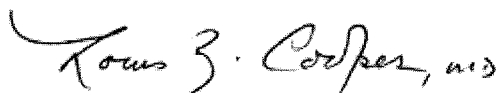
On behalf of the 57,000 pediatricians represented by the American Academy of Pediatrics, I write to express our opposition to efforts by the Food and Drug Administration to reclassify colored contact lenses that do not correct vision as cosmetics instead of medical devices.

In the image-conscious world of adolescence, non-corrective colored contact lenses are viewed as a harmless novelty. However, like prescription contact lenses, there are significant risks with improperly using lenses and use can result in medical complications such as severe infections, ulceration, lacerations or in extreme cases, scarring of the cornea. In addition, the shape and size of the eyeball differs from individual to individual, making a "one size fits all" over-the-counter approach to providing contact lenses risky.

It is essential that anyone wearing any kind of contact lenses be properly fitted for those lenses and receive guidance from medical professionals as to their appropriate use. If the wearer does not adhere to specific medical and safety precautions (i.e., proper sanitation of the lenses, limiting hours of daily use, etc.) their risk of complications is greatly increased and can result in short and long term health implications ranging from eye pain to serious cornea disease and even blindness.

To reclassify colored contact lenses that do not correct vision from a device to a cosmetic undermines the public health protections that the Food and Drug Administration has been charged with upholding. The American Academy of Pediatrics strongly urges you to withdraw any plans to reclassify this device.

Sincerely,

A handwritten signature in dark ink, reading "Louis Z. Cooper, MD". The signature is fluid and cursive, with the first name "Louis" and last name "Cooper" clearly legible, followed by "MD" in smaller letters.

Louis Z. Cooper, MD, FAAP
President



8201 Corporate Drive
Suite 850
Landover, MD 20785

September 11, 2002

The Honorable Tommy Thompson
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Room 615-F
Washington, DC 20201

PHONE
301-459-1800

FAX
301-459-1802

cli@us.net

Dear Secretary Thompson:

I am writing to convey the serious concern of the Contact Lens Institute ("CLI") with recently reported proposals to reclassify certain types of contact lenses and to treat them as "cosmetics" exempt from all medical device standards and from prescription-only status. CLI is an association of research-oriented manufacturers of contact lens and lens care products, whose members are Alcon, Advanced Medical Optics (formally Allergan), Bausch and Lomb, CIBA Vision, CooperVision and Vistakon (a division of Johnson and Johnson).

As manufacturers of virtually all of the currently marketed products that could be affected by such action, the members of CLI strongly believe that these proposals would significantly compromise the essential public health safeguards maintained by the FDA through its consistent and long-standing classification of all contact lens products as prescription-only medical devices. These proposals also would require the FDA to contradict its previously consistent and forceful public health warnings reinforcing the need for professional fitting of contact lenses and supervision of contact lens wear, including lenses intended to change or enhance the appearance of the eye. (See the attached "FDA Public Health Notification: Illegal Promotion of Contact Lenses," September 25, 1998)

CLI legal counsel have previously addressed these concerns to Mr. Troy and Dr. Feigal at the FDA. (See the attached Email message dated August 26, 2002.) In that communication, CLI also specifically requested that FDA provide public notice of the scope of and basis for any proposed change and an opportunity to comment prior to its implementation. We have, to date, received no response from the FDA.

We encourage you to assure that proper consideration is given to the risks that deregulation of these contact lens products would pose for the health of potential users. It is CLI's opinion that, from a public health and legal perspective, these lenses should continue to be regulated as prescription devices. In addition, a contrary interpretation could have a detrimental precedential effect on FDA's ability to maintain effective jurisdiction over other important products, the intended use of which can also negatively affect the structure and function of vital body organs and whose proper design, manufacture and safe use depend in significant part on their regulation by FDA as drugs and/or medical devices.

Sincerely,


Edward L. Schilling, III
Executive Director

cc: Eve Slater, Assistant Secretary, HHS (fax – 202/690-7203)
Lester Crawford, Deputy Commissioner, FDA (fax – 301/443-3100)
Daniel E. Troy, Esq., Chief Counsel, FDA (fax – 301/827-1137)
David W. Feigal, Jr. Director, CDRH (fax – 301/594-1320)
Thomas O. Henteleff, Esq.
Peter R. Mathers, Esq.



The Honorable Henry A. Waxman
Ranking Minority Member
Congress of the United States
House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Attention: Dr. Josh Sharfstein
Committee on Government Reform

CIBA Vision Corporation
Legal Department
11460 Johns Creek Parkway
Duluth, Georgia 30097-1556

R. Scott Meece
Vice President & General Counsel
Voice: 678-415-3054
Fax: 678-415-3018
scott.meece@cibavision.novartis.com

VIA FACSIMILE TO (202) 226-3348

August 27, 2002

Dear Congressman Waxman:

I read with great interest your letter dated August 26, 2002 to The Honorable Tommy G. Thompson. On behalf of CIBA Vision Corporation, I express our full support of your position that plano colored contact lenses should continue to be regulated by the FDA and prescribed by licensed eye care practitioners.

The manufacture and sale of contact lenses is the core of our business. Our business exists because consumers can safely wear our contact lenses, whether the lenses correct vision, provide cosmetic benefits or both. We firmly believe and consistently communicate that all contact lens wearers should visit their eye care practitioner for proper lens fitting, as well as wearing and cleaning instructions. In addition, every wearer should have regular, periodic examinations to ensure that their lenses continue to fit properly and that ocular health is not compromised. We believe this practice is important to our business, but more importantly, this practice is important for maintaining the ocular health and good vision of contact lens wearers.

You should know that we have initiated a project within our company - Project Healthy Eyes - whose goals are aligned with the position taken in your August 26 letter. Therefore, I offer our support of your position, and I invite you to contact me if you believe we can do anything further to support this effort.

Our company's guiding purpose is to improve, protect and preserve the eyesight of people around the world. We are truly proud of this purpose. We see your position on this issue as being in line with our goals, and on behalf of our employees and contact lens wearers, I thank you for your work.

Sincerely,

R. Scott Meece
Vice President & General Counsel



September 11, 2002

The Honorable Tommy G. Thompson, Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Secretary:

Prevent Blindness America is alarmed by the recent news that the Food and Drug Administration (FDA) is considering reclassifying tinted plano contact lenses as cosmetics instead of medical devices. This would be a very harmful policy decision for consumers.

Statistics show that in 2001, there were an estimated 1,500 injuries related to contact lenses treated in U.S. hospital emergency rooms. That figure is very low as many people are treated in doctor's offices, clinics, or not at all. It is hard to say how many of these injuries were caused by cosmetic lenses, but precautions must be taken with any kind of contact lenses.

Unauthorized plano contact lenses are already being sold on the beach, at flea markets and on the Internet illegally. Teens are the primary consumers of these colorful cosmetic lenses and there has been a rising incidence of serious eye injuries as a result. The array of colors and patterns is a tempting fashion statement for teens that are not aware of the dangers associated with ill-fitting or poorly manufactured contact lenses.

Problems associated with improperly fitted lenses include decreased flow of oxygen to the cornea, bacterial infections, swelling, eye pain, sensitivity to light, conjunctivitis (pink eye), corneal scratches, corneal ulceration, and loss of clarity. If left untreated, these conditions can result in permanent eye damage and loss of sight.

If consumers are able to purchase these contact lenses without a prescription legally, the number of eye injuries will skyrocket. Companies eager to make money will capitalize on this freedom at the expense of innocent consumers. Shouldn't the government do everything they can to protect our nation's youth from health dangers?

As the nation's leading volunteer eye health organization, Prevent Blindness America is extremely concerned that many of the millions of people we serve every year will be hurt or perhaps even lose their sight if the FDA goes through with this policy change. Our nation's health would be best served if the FDA continues to regulate plano lenses as prescription medical devices. Thank you for your consideration of this crucial issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Hugh R. Parry". The signature is fluid and cursive, with the first name "Hugh" being the most prominent.

Hugh R. Parry
President & CEO